## REMARKS

This is a full and timely response to the non-final Official Action mailed June 15, 2006. Reconsideration of the application in light of the above amendments and the following remarks is respectfully requested.

Claim Status:

By the foregoing amendment, claims 1 and 38 have been amended. No new claims have been added. Claims 39-40 have been cancelled herein without prejudice or disclaimer. Applicant reserves the right to file any number of continuation or divisional applications to the canceled claims or to any other subject matter described in the present application. Claims 6, 7 and 9-13 were canceled previously without prejudice or disclaimer. Thus, claims 1-5, 8, 14-16, 36-38, and 41 are currently pending for further action.

Non-responsiveness of Previous Response:

In a previous restriction requirement, Applicant selected "headache" as the species to be examined in the event that the generic claim 1 was not found to be allowable. Thus, Applicant's previous response of March 27, 2006 was found to be not fully responsive to the Office Action of October 6, 2005 because the term "headache" was removed from claim 1. In response, Applicant has amended claim 1 herein to include "headache" as well as other species (disorders) previously included in claim 1. Independent claim 38 has been similarly amended to include the disorders previously included in claim 1. Hence, claims 1 and 38 are now generic to "headache" and all other disorders contained therein. Following entry of this amendment, the reply to the Office Action of October 6, 2005 should be fully responsive, and notice to that effect is respectfully requested.

Claim Rejections – 35 U.S.C. § 103:

In the Office Action of October 6, 2005, claims 1-5, 8, and 14-16 were rejected as unpatentable under 35 U.S.C. § 103(a) in view of U.S. Patent No. 5,312,439 to Loeb ("Loeb") or U.S. Patent No. 5,324,316 to Schulman et al. ("Schulman"), each in view of U.S. Patent No. 5,928,272 to Adkins et al. ("Adkins"), U.S. Patent No. 5,540,730 to Terry, Jr. et al. ("Terry-1"), U.S. Patent No. 5,330,507 to Schwartz et al. ("Schwartz"), U.S. Patent No. 5,335,657 to Terry, Jr. et al. ("Terry-2"), or U.S. Patent No. 5,330,515 to Rutecki et al. ("Rutecki"). In addition to Applicant's arguments already filed in response to the Office Action of October 6, 2005, this rejection is respectfully traversed for at least the following reasons.

Claim 1, as amended herein, recites:

> A method of treating a patient with at least one of epilepsy, a metabolic disorder, a mood disorder, an anxiety disorder, chronic pain, a gastrointestinal disorder, hypertension, a cardiac disorder, a psychotic disorder, a cognitive disorder, dementia, an eating disorder, obesity, a sleep disorder, an endocrine disorder, a movement disorder, and headache, the method comprising:
>
> providing at least one leadless stimulator having at least two electrodes disposed thereon;
>
> implanting the at least one stimulator adjacent to at least one portion of the patient's vagus nerve;
>
> generating stimulation pulses with the stimulator in accordance with one or more stimulation parameters; and
>
> delivering the stimulation pulses to nerve fibers adjacent to at least one portion of the vagus nerve.

(emphasis added).

In contrast, the combination of Loeb or Schulman with Adkins, Terry-1, Schwartz, Terry-2, or Rutecki fail to teach or suggest stimulating a patient's vagus nerve with a ***leadless*** implantable stimulator in order to treat epilepsy, a metabolic disorder, a mood disorder, an anxiety disorder, chronic pain, a gastrointestinal disorder, hypertension, a cardiac disorder, a

psychotic disorder, a cognitive disorder, dementia, an eating disorder, obesity, a sleep disorder, an endocrine disorder, a movement disorder, or headache for the following reasons:

A. Prior art does not enable or teach claimed invention or motivate modification; improper hindsight reconstruction

According to the Office Action, the teachings of Loeb or Schulman with Adkins, Terry-1, Schwartz, Terry-2, or Rutecki may be combined to render obvious the method of stimulating the vagus nerve with a leadless implantable stimulator as recited in claim 1. Applicant respectfully disagrees. Combining elements "in a manner that reconstructs the applicant's invention only, with the benefit of hindsight, is insufficient to present a *prima facie* case of obviousness. There must be some reason, suggestion, or motivation found in the prior art whereby a person of ordinary skill in the field of the invention would make the combination. That knowledge cannot come from the applicant's invention itself." *In re Oetiker*, 24 USPQ2d 1443, 1447 (Fed. Cir. 1992) (citations omitted).

Applicant respectfully submits that none of the cited prior art provides a reason, suggestion, or motivation to stimulate the vagus nerve with a *leadless* implantable stimulator. For example, although Loeb and Schulman disclose a leadless microstimulator, none of the cited prior art teaches, suggests, or gives a motivation to use such a microstimulator to stimulate the vagus nerve. Rather, each of the cited prior art references specifically teaches using a stimulating device with a *lead* to apply electrical stimulation to the vagus nerve. (see, e.g., Adkins, col. 2, lines 28-52; Terry-1, col. 4, lines 5-26; Terry-2, col. 8, lines 2-5; Schwartz, col. 5, lines 13-39; or Rutecki col. 8, lines 42-64).

Applicant's assertion that none of the cited prior art provides a reason, suggestion, or motivation to stimulate the vagus nerve with a leadless implantable stimulator is further

supported by the subject matter taught in Adkins. Adkins discloses a stimulating device configured to stimulate the vagus nerve in accordance with cardiac activity as sensed by one or more sensing electrodes. (Adkins, col. 4, lines 24-37). These sensing electrodes are "located at predetermined spaced-apart points along the exterior of the device case, and not on a separate lead or leads external to the case. *As a result, the only lead required to be implanted in the patient is the lead associated with the electrode array to be implanted on the vagus (or other cranial) nerve for stimulation thereof.*" (Adkins, col. 4, lines 41-47, emphasis added). The leadless electrodes disclosed in Adkins are *only* configured to sense cardiac activity. There is no reason, suggestion, or motivation given in Adkins to also use the leadless electrodes to stimulate the vagus nerve. Rather, Adkins requires the use of a lead for stimulation thereof, despite the fact that the Adkins application was filed approximately four years after both Loeb and Schulman issued as patents.

Hence, the combination of Loeb or Schulman with Adkins, Terry-1, Schwartz, Terry-2, or Rutecki fails to suggest the desirability of stimulating the vagus nerve with a leadless stimulator as recited in claim 1. Although the Office Action concludes that the combination of the cited prior art makes obvious the claimed invention, it has not shown that there is any teaching or suggestion in any of the references, or in the prior art as a whole, of the desirability that would lead one with ordinary skill in the art to make the combination. "The Commissioner bears the burden of *showing* that such knowledge provided some teaching, suggestion, or motivation to make the particular combination that was made by the applicant." *In re Raynes* 28 USPQ2d 1630, 1632 (Fed. Cir. 1993) (citations omitted; emphasis added). Thus, applicant submits that the Examiner's motivation to modify the references to arrive at the presently claimed invention derives from hindsight based on

applicant's disclosure, as no "showing" has been made that the prior art suggests the desirability of the claimed combination.

B. A reasonable expectation of success is not found in the prior art; obvious to try is an improper standard

The Office Action has failed to show a reasonable expectation of success in the prior art with regard to stimulating the vagus nerve with a leadless implantable stimulator. A reasonable expectation of success is the standard with which obviousness is determined, and as MPEP § 2142 clarifies:

> [t]he reasonable expectation of success must be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Using the CCPA evaluation of a prima facie case of obviousness, first, a determination is made whether "the references by themselves...suggest doing what appellants have done." *In re Clinton*, 527 F.2d 1226, 1228, 118 USPQ 365, 367 (CCPA 1976). The CCPA next considered whether a person of ordinary skill in the art would have had a basis for the required reasonable expectation of success: "Obviousness does not require absolute predictability but a reasonable expectation of success is necessary." *Id.*, 527 F.2d at 1228, 118 USPQ at 367. This requirement that there be a reasonable expectation of success follows from the court's requirement in *In re Tomlinson*, 150 USPQ 623 (CCPA 1966), that the prior art or surrounding circumstances must have made any proposed modification or changes in the prior art obvious to do rather than obvious to try. The court in *Tomlinson* stated:

> ...we think that there is usually an element of 'obviousness to try' in any research endeavor...and that patentability determinations based on that as the test would not only be contrary to the statute but would result in a marked deterioration of the entire

> patent system as an incentive to invest in those efforts and attempts which go by the name 'research'.

*Id.* at 626. Thus, "whether a particular combination might be 'obvious to try' is not a legitimate test of *patentability*." *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988) (citations omitted; emphasis added).

As further described in MPEP § 2145, an "obvious to try" standard has been improperly applied to 35 U.S.C. 103, mainly in two situations: suggesting that it is obvious 1) to "try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave...no direction as to which of many possible choices is likely to be successful" or 2) "to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it. *In re O'Farrell*, 853 F.2d 894, 903, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988) (citations omitted)."

The assertion in the Office Action that it would have been obvious to one of ordinary skill in the art to take the Loeb or Schulman device and substitute it for one of the leaded devices in Adkins, Terry-1, Schwartz, Terry-2, or Rutecki is an unsupported conclusion. "The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1420 (Fed. Cir. 1990)." M.P.E.P. § 2143.01. Hence, although the Loeb and Schulman devices may be implanted in any part of the body, the cited prior art fails to give any direction as to how to achieve vagus nerve stimulation with a leadless stimulator, and is further evidenced by the lack of content directed to leadless stimulators disclosed in Adkins, Terry-1, Schwartz, Terry-2, and Rutecki.

Conclusion:

For the foregoing reasons, the present application is thought to be clearly in condition for allowance. Accordingly, favorable reconsideration of the application in light of these remarks is courteously solicited. If any fees are owed in connection with this paper which have not been elsewhere authorized, authorization is hereby given to charge those fees to Deposit Account 18-0013 in the name of Rader, Fishman & Grauer PLLC. If the Examiner has any comments or suggestions which could place this application in even better form, the Examiner is requested to telephone the undersigned attorney at the number listed below.

Respectfully submitted,

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**CERTIFICATE OF TRANSMISSION**

I hereby certify that this correspondence is being transmitted to the Patent and Trademark Office facsimile number 571-273-8300 on July 17, 2006. Number of Pages: 16

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